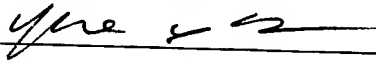


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NEEDLE PROTECTOR

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[0001] This application claims the benefit of United States Provisional Patent Application Serial No. 60/402,286, filed August 9, 2002.

[0002] The present invention relates generally to protective devices (i.e., needle protectors) for use with medical needles to prevent inadvertent user contact with such needles.

BACKGROUND OF THE INVENTION

[0003] Needle protectors are well known in the field of blood donation. Needle protectors are used to shield a used needle and, thereby, protect the medical personnel from an accidental needle stick.

blood donation or collection kit, which includes a needle attached to one end of a needle hub. The other end of the need hub is attached to a length of plastic tubing that provides a flow path to one or more containers used to collect the donated blood. The needle protector is often provided as a sleeve placed around the plastic tube. The plastic tube extends through the needle protector, entering through one open end and exiting through an opposite open end.

[0005] After blood donation, the tube is pulled by the medical technician to retract the needle and needle hub into the needle protector. The used needle is, thus, shielded from the medical technician.

[0006] U.S. Patent Nos. 5,800,400, 6,042,570, and 6,165,157 are just a few of the many examples of known needle protectors. The needle protectors disclosed therein, and in other U.S. patents, include features to provide protection of medical personnel from accidental needle sticks. The needle protectors may also include features which prevent movement of the needle during blood donation, which could cause discomfort to the donor.

[0007] For example, U.S. Patent No. 6,165,157 describes a needle protector that includes restraining means which restrain movement of the needle hub when the needle is inserted in the arm of the donor. The needle protector also includes locking means to secure

the used needle in a completely shielded position after use.

[0008] While needle protectors such as those described above in the aforementioned patents have worked satisfactorily, efforts continue to provide a needle protector that assures the safety of the medical technician, is easy for the technician to manipulate and/or operate, and provides maximum comfort to the donor. Efforts continue to provide a needle protector that achieves these ends and combines them in a needle protector that is also easy and inexpensive to manufacture and easy to use by the medical personnel.

SUMMARY OF THE INVENTION

[0009] In one aspect, the present invention is directed to a blood collection needle protector for use with a needle assembly that includes a needle and hub, and a blood collection tube attached to the hub. The blood collection needle protector includes a unitary body including first and second open ends. The needle protector further includes a plurality of side walls extending between the first and second open ends, the side walls defining an interior chamber within the body. The first open end of the needle protector is adapted to receive the hub of the needle assembly. One of the side walls includes a retaining member adapted for contacting the hub. The needle protector also includes a side wall that defines a slot to allow viewing of the interior

chamber of the needle protector.

[00010] In another aspect, the present invention is directed to a blood collection needle protector assembly that includes the above-described needle protector and a needle assembly that includes a needle, a hub and a blood collection tube attached to the hub. The body of the hub and further includes a outwardly extending rib.

[00011] In other more specific aspects, the present invention includes the above-described needle protector that further includes a needle protector wherein the side walls include first and second guiding ledges extending inwardly from the side walls. In another aspect, the needle protector includes an axial groove in one of the side walls.

[00012] In another aspect, the other second open end of the needle protector may include a multiple profile window adapted to slidably receive and secure the blood collection tube.

BRIEF DESCRIPTION OF THE DRAWINGS

[00013] Fig. 1 is a plan view of a blood collection kit, including containers for collecting blood and a needle protector embodying the present invention;

[00014] Fig. 2 is a perspective view of the needle protector embodying the present invention in association with a needle assembly;

[00015] Fig. 3 is a perspective view of the needle protector

embodying the present invention;

[00016] Fig. 4 is a front perspective view of the needle protector of Fig. 3;

[00017] Fig. 5 is a rear perspective view of the needle protector of Fig. 3;

[00018] Fig. 6 is a cross-sectional side view of the needle protector embodying the present invention in association with a needle assembly;

[00019] Fig. 7 is a front perspective view of the needle protector in combination with a needle assembly;

[00020] Fig. 8 is a front perspective view of the needle protector in combination with the needle assembly wherein the needle hub is rotated 180°;

[00021] Fig. 9 is a perspective view of one embodiment of the needle protector of the present invention including an end cap; and

[00022] Fig. 10 is a perspective view of another embodiment of the needle protector of the present invention including an end cap.

DETAILED DESCRIPTION OF THE DRAWINGS

[00023] The needle protector of the present invention will be described below in the context of its preferred use, namely, as a needle protector that is part of a disposable tubing and container set intended for the collection and processing of blood (or other biological fluid). It will be understood that the needle protector

of the present invention is not limited to use with disposable tubing and container sets of the type shown in, for example, Fig.

1. In fact, the needle protector of the present invention may be used in any blood collection, donation, processing or treatment method and with any devices and tubing sets used for practicing such methods.

[00024] Also, as used herein, the term "needle" refers to any elongated member having a sharpened tip for puncturing or piercing. The term "needle" is not limited to traditional venipuncture needles, which are typically made of stainless steel and are relatively small in diameter. Although the term "needle" includes such venipuncture needles, it also includes piercing members made from other materials, such as plastic, and includes cannulas, coupling devices and the like.

[00025] Turning now to the drawings, Fig. 1 shows an exemplary disposable tubing and container set 10 for collecting blood from a donor 11. The illustrated disposable set may include a needle, such as a venipuncture needle 12, and a plastic tubing segment 16 attached to needle 12 and extending from needle 12 to a plastic, blood collection container 18. Although not shown in Fig. 1, needle 12 may be attached to one end of a needle hub and tubing 16 is attached to the other end of a needle hub (as shown, for example, in Fig. 2).

[00026] The disposable blood processing set may include a single blood collection container 18, or more commonly, as shown in Fig. 1, may include a primary container and additional, integrally attached containers 20 and 22, as is well known in the field. The methods and disposable sets for practicing such methods are well known and will not be discussed here. They are described in U.S. Patent Nos. 4,222,379, 5,445,629 and 6,387,086, all of which are incorporated by reference herein. As noted above, however, the needle protector of the present invention is not limited to use with such blood collection kits, but may also be used in connection with other apparatus and methods used in the processing, treatment and collection of blood or other biological fluid.

[00027] Also, shown in Fig. 1 is a needle protector 40 embodying the present invention. As shown in Fig. 1, needle protector 40 is placed on or otherwise associated with tubing 16, which leads from the venipuncture needle to one or more collection containers. More specifically, needle protector 40 provides a sleeve that is relatively moveable with tubing 16, as described in more detail below.

[00028] Turning now to Fig. 2, there is shown a needle protector 40 which includes a body 42 having an open distal end 44 and open proximal end 46 (best seen in Fig. 5). Open distal and proximal ends 44 and 46, respectively, are adapted and sized to receive

tubing 16 of the blood tubing set 10. As shown, for example, in Fig. 2, distal end 44 includes a larger opening adapted for and of sufficient size to receive the needle hub 20. On the other hand, open proximal end 46 is sized so that hub 20 cannot exit through the proximal end 46. As shown in Fig. 5, open proximal end 46 may include a multi-profile window, including a portion 47 having a smaller diameter and a portion 49 having a larger diameter. The multi-profile window is discussed in greater detail below.

[00029] Returning now to Figs. 2 and 3, needle protector 40, and specifically body 42, includes a plurality of side walls 48, 50, 52 and 54. The outer surfaces of side walls define a needle protector body 42 with a generally rectangular shape. The inner surfaces of side walls 48, 50, 52 and 54 define an interior chamber 56 (Fig. 3) for receiving the needle assembly (i.e. needle 12, hub 20 and tubing 16). Of course, needle protector 40 can have any shape including, but not limited to, a cylindrical tube shape defined, for example, by a continuous arcuate wall.

[00030] As further seen in Figs. 2 and 3, needle protector 40 may include retaining member 60 and a viewing slot 62. Preferably, retaining member 60 and viewing slot 62 are formed in top wall 48 near the proximal end 46 of needle protector 40.

[00031] Needle protector 40 may further include a outwardly extending flange 58 at the open distal end 44 of needle protector

40. Outwardly extending flange 58 allows the needle protector 40 to be locked inside a sampling tube holder, as shown and described in U.S. Patent Application Serial No. 09/442,210, filed November 17, 1999, incorporated by reference herein.

[00032] Turning now to Figs. 4, 6, 7 and 8, needle protector 40 may also include guiding ledges 68 and 70. Guiding ledges 68 and 70 may be provided as outwardly extending lips that protrude from side walls 50 and 52 and/or depend downwardly from top wall 48. Guiding ledges 68 and 70 may span the entire length of the needle protector 40 from distal end 44 to proximal end 46. At the minimum, guiding ledges 68 and 70 may extend from distal end 44 substantially up to the proximal tip of retaining member 60. Guiding ledges 68 and 70 "guide" needle hub 20 as it is being retracted into needle protector 40 and prevent hub 20 from rotating once inside the needle protector 40.

[00033] As further shown in Figs. 4 and 8, needle protector 40 may include a longitudinal groove 72 in one of the side walls of the needle protector 40. Preferably, groove 72 extends substantially the entire length (from distal end 44 to proximal end 46) and is formed in bottom wall 54 of needle protector 40. In the event that hub 20 has been inverted 180° as it enters protector 40), groove 72 is provided to receive and accommodate rib 22 of hub 20. Groove 72 allows hub 20 to be retracted, even in the inverted

position, into needle protector 40, without interference from guiding ledges 68 and 70.

[00034] It will be appreciated that the locations of guiding ledges of 68 and 70 and groove 72 may be inverted. For example, guiding ledges 68 and 70 may extend externally from side walls 50 and 52, but at a location closer to bottom wall 54. Conversely, groove 72 may be formed in top wall 48.

[00035] Turning now to Fig. 6, there is shown a needle protector assembly including a needle hub 20, a needle 12, (and a length of tubing extending from the one end of hub 20) fully retracted into needle protector 40. As shown in Fig. 6, retraction of hub 20 beyond retaining member 60 provides a locked and secured needle within needle protector 40. Full and complete retraction of the needle hub into the locked position is evidenced by an audible "click" sound caused by the snapping of retaining member 60 as hub 20 clears the proximal tip end 61 of retaining member 60. Retaining member 60 is sufficiently flexible and resilient such that it will not restrict movement of hub 20 in the direction of the proximal end 46 during retraction. Retaining member 60 may be a detent that extends downwardly from side wall 48 into interior chamber 56 in the direction of proximal end 46. Retaining member 60 may depend downwardly at an angle relative to sidewall 48. Retaining member 60 acts as a catch and prevents movement of hub 20

back out through open distal end 44. Whether the needle hub has been securely locked can also be ascertained by visual observation through viewing slot 62.

[00036] Turning now to Fig. 5, a multi-profile window in open proximal end 46 is provided to receive and retain tubing 16 of the blood tubing set 10. The multi-profile window allows for easy threading of tubing 16 through needle protector 40 during assembly of the kit. It also provides a means for more firmly holding the tubing when necessary. For example, when threading the tubing during assembly or when retracting the needle assembly into needle protector 40 after donation, the larger profile 49 provides sufficient space to allow for easy retraction or movement of the tubing relative to needle protector 40. The smaller profile window 47 may be used to secure the tubing and substantially prevent relative movement of the needle assembly and protector 40 during, for example, manufacture, shipping and/or blood donation. Specifically, tubing 16 may be press-fit into the smaller profile window 47 to prevent relative movement of the tubing and protector 40. Of course, during blood donation, relative movement of needle protector 40 and tube 16 may also be achieved by simply taping tubing 16 to the arm of the donor.

[00037] Needle protector 40 is preferably a unitary needle protector. By "unitary," it is meant that needle protector 40 is

made of a single piece construction and is not made up of two or more joined or separable parts. Needle protector may be made by casting, or more preferably, injection molding, or by other means that will be known to those of skill in the art. Needle protector 40 may be made of any material that is suitably rigid and puncture resistant and suitable for use in the medical field. For example, needle protector 40 may be made of any thermoplastic material that can be sterilized by known sterilization techniques, including, but not limited to autoclaving, gamma radiation or electron beam radiation.

[00038] For example, needle protector 40 may be made of a polyolefin material, such as, most preferably, polypropylene. Other suitable materials may include polyethylene, such as high density polyethylene, polyacetal and polycarbonate. Of course, needle protector 40 may also be made of blends of two or more of the above-described materials. Preferably, the material used for needle protector 40 may be transparent to allow for viewing of the interior chamber of needle protector 40.

[00039] Figs. 9 and 10 show the needle protector of the present invention including an end cap 80 attached to needle protector 40 at the distal end 44. Cap 80 may be attached to needle protector 40 by hinges attached to a sidewall of needle protector 40. In one embodiment, cap 80 may be attached to sidewall 48 (or 54). In

another embodiment, cap 80 may be attached to either sidewall 50 or 52. Cap 80 may be attached to needle protector 40 and, specifically, sidewalls by a hinge(s) 82. Hinge 82 is preferably a living hinge which snaps cap 80 open or closed by a simple flick with a finger. This allows easy, one-handed operation of needle protector 40. Cap 80 may preferably be further provided with a lip 84. Lip 84 allows the technician to open and close cap 80 in the manner described above. Finally, cap 80 may also include gripping members 86 to provide some friction with the user's fingers when cap 80 is being closed.

[00040] Blood donation using a disposable processing set with the needle protector of the present invention begins with the technician disinfecting an area of the donor's arm. Needle 12 is then inserted into the vein at the disinfected area, with needle protector 40 slidably spaced from needle 12. While maintaining the needle in the inserted and correct position, the technician will slide needle protector 40 along tubing 16 toward needle 12 so as to partially enclose hub 20 within needle protector 40.

[00041] Typically, the technician will place a strip of adhesive tape over, for example, side wall 48 and adhere the ends of the tape to the donor's skin. This maintains needle protector 40 in place on the donor's arm during the blood donation. The technician may also, optionally, press tubing 16 into small profile window 47

or secure tube 16 to the donor's arm with tape, as previously described.

[00042] When donation is complete, the technician may withdraw needle 12 from the donor's arm by simply pulling tubing 16 with one hand while gently pressing down on needle protector 40 with the other hand. Needle 12 is retracted until needle hub 20 has passed retaining member 60 and a "click" is heard.

[00043] Once needle 12 has been firmly secured within protector 40, the technician will remove the tape and treat the punctured area of the donor's arm. The secured needle protector may, optionally, then be placed into a sampling tube holder, as described in U.S. Patent Application Serial No. 09/442,210, previously incorporated by reference. Thus, needle protector 40 allows for smooth and easy retraction of the needle hub assembly from the donor when donation is completed, and minimizes the risk of accidental needle stick.

[00044] While the present invention has been described in connection with the foregoing embodiments, it is to be understood that the invention is not limited thereto, but is intended to include various modifications and equivalent arrangements thereto.